DATA REVIEW FOR PRIMARY DERMAL IRRITATION (870.2500, previously §81-5)

Product Manager: 23
MRID No.: 45086102

Reviewer: Byron T. Backus, Ph.D.
Amended Report Date: March 30, 2000
Study No.: 00-0661-G2

Testing Facility: Toxikon Corporation, Bedford, MA 01730
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Quality Assurance (40 CFR §160.12): Included (p. 6)

Test Material: Admiral WSP; Lot/Batch #: 10673; a dark blue powder
Dosage: 0.5 g
Species: Rabbit; New Zealand White
Ages: Adult (at least 10 weeks old)
Weight: 2.19-2.24 kg
Source: Millbrook Breeding Labs, Amherst, MA

Conclusion:

1. **Toxicity Category:** IV
2. **Classification:** Acceptable

Procedure (including deviations from 870.2500): "The application sites were prepared by clipping the skin of the dorsal area of the trunk free of hair approximately 24 hours before application of the test substance. The site of application was not abraded deliberately nor accidentally during preparation."

"A dose of 0.5 g of the solid (powder) test substance was applied to each application site. The test substance was used undiluted... The test substance was applied to a small area (approximately 6 cm^2) of skin and covered with a gauze patch, which was held in place with non-irritating tape. The test substance was applied to the gauze patch and then applied to the skin. The patch was loosely held in contact with the skin by means of a suitable semiocclusive dressing for the duration of the exposure period. Access by the animal to the patch resulting in the ingestion/inhalation of the test substance was prevented."

The exposure period was 4 hours.

"After the exposure period, residual test substance was removed and the skin was wiped with USP Water for Injection..."

Results: All scores were 0 for erythema and edema at all scoring times (30-60 minutes after removal of the test substance; 24, 48 and 72 hrs.

Special Comments: None

ACUTE TOX ONE-LINERS

1. **DP BARCODE:** D267113
2. **PC CODES:** 110301 Erioglaucine; 110302 Tartrazine
3. **CURRENT DATE:** October 10, 2000
4. **TEST MATERIAL:** ADMIRAL.WSP; a dark blue powder; identified [MRID 45144401] as containing 68.21% blue dye; 4.62% yellow dye

Study/Species/Lab Study #/Date	MRID	Results	Tox. Cat.	Core Grade
Acute Dermal Toxicity/Rabbit/MB Research Laboratories/MB 00-8314.02/JUN-05-2000	45144401	LD_{50} > 2000 mg/kg (no mortalities in 5M, 5F rabbits). Diarrhea, few feces, soiling of the anogenital area and blue staining of feces noted during observation period. Blue staining of the dose site noted in all animals through day 14. Unspecified "treated skin abnormalities" in all animals at necropsy.	III	A
Primary Eye Irritation/Rabbit/ Toxikon Corp./00-0661-G1/MAR-30-2000	45086101	3 rabbits used; one summary (p. 13) states slight irritation observed in all treated eyes at 1 hr, resolving by 48 hrs. Other statement (p. 13) is that no signs of irritation were noted at any time.	III*	A
Primary dermal irritation/Toxikon Corp./00-0661-G2/MAR-30-2000	45086102	No irritation. PII = 0.0	IV	A

*Before this formulation can be reclassified as toxicity category IV in terms of eye irritation potential, apparent inconsistencies in the reporting in MRID 45086101 should be clarified.
Core Grade Key: **A =Acceptable, S = Supplementary, U = Unacceptable, V = Self Validated**